

Please type a plus sign (+) inside this box → ☐

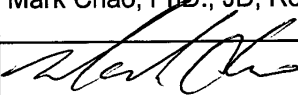
PTO/SB/21 (08-00)


Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	09/673,958
	Filing Date	10/19/2000
	First Named Inventor	NAMBA, M.
	Group Art Unit	tba
	Examiner Name	tba
Total Number of Pages in This Submission	Attorney Docket Number	2519 US0P

ENCLOSURES <i>(check all that apply)</i>		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input checked="" type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers <i>(for an Application)</i> <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group <i>(Appeal Notice, Brief, Reply Brief)</i> <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) <i>(please identify below):</i> Return Postcard. <i>EXECUTED DECLARATION</i>
Remarks		The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 500799.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Mark Chao, PhD., JD, Reg. No. 37,293
Signature	
Date	8/13/01

CERTIFICATE OF MAILING		
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: 8/13/01		
Typed or printed name	<i>Mark Chao</i>	
Signature		Date 8/13/01

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments  
on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington,  
DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**FEE TRANSMITTAL  
for FY 2001**

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT

(\$) 130 -

**Complete if Known**

Application Number	09/673,958
Filing Date	10/19/2000
First Named Inventor	NANBA, M.
Examiner Name	tba
Group Art Unit	tba
Attorney Docket No.	2519 US0P

**METHOD OF PAYMENT**

- 1.
- ☒
- The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit  
Account  
Number

500799

Deposit  
Account  
Name

Takeda Chemical Indus. Ltd

- ☒
- Charge Any Additional Fee Required
- 
- Under 37 CFR 1.16 and 1.17

☐ Applicant claims small entity status.  
See 37 CFR 1.27

- 2.
- ☐
- Payment Enclosed:

☐ Check ☐ Credit card ☐ Money  
Order ☐ Other**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Small Entity

Fee Fee Fee Fee Fee Description  
Code (\$) Code (\$)

101 710 201 355 Utility filing fee

106 320 206 160 Design filing fee

107 490 207 245 Plant filing fee

108 710 208 355 Reissue filing fee

114 150 214 75 Provisional filing fee

Fee Paid

SUBTOTAL (1) (\$)

**2. EXTRA CLAIM FEES**

Total Claims		-20** =		X	Fee from below	=	Fee Paid
Independent Claims		-3** =		X		=	
Multiple Dependent						=	

Large Entity Small Entity

Fee Fee Fee Fee Fee Description  
Code (\$) Code (\$)

103 18 203 9 Claims in excess of 20

102 80 202 40 Independent claims in excess of 3

104 270 204 135 Multiple dependent claim, if not paid

109 80 209 40 \*\* Reissue independent claims  
over original patent110 18 210 9 \*\* Reissue claims in excess of 20  
and over original patent

SUBTOTAL (2) (\$)

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION (continued)****3. ADDITIONAL FEES**

Fee Code	Large Entity (\$)	Fee Code	Small Entity (\$)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	130 -
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for ex parte reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	390	216	195	Extension for reply within second month	
117	890	217	445	Extension for reply within third month	
118	1,390	218	695	Extension for reply within fourth month	
128	1,890	228	945	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,240	241	620	Petition to revive - unintentional	
142	1,240	242	620	Utility issue fee (or reissue)	
143	440	243	220	Design issue fee	
144	600	244	300	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Processing fee under 37 CFR 1.17(q)	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	710	246	355	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	710	249	355	For each additional invention to be examined (37 CFR § 1.129(b))	
179	710	279	355	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

130 -

**SUBMITTED BY**

Name (Print/Type)

Mark Chao

Registration No.  
(Attorney/Agent)

37,293

**Complete (if applicable)**

Telephone

877 393 3372

Signature

Date

8/10/01

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Express Mail #EL 79268865345

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	09/673,958	Art Unit:	tba
Filed:	10/19/2000	Examiner:	tba
1 <sup>st</sup> Inventor:	M. NANBA	Allowed:	
For:	A Human Derived Immortalized Liver Cell Line	Batch:	
Atty. Dkt. No.	2519 USOP	Paper No.:	

#6

**CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10****USPS EXPRESS MAIL LABEL. No. EL 792688653 US****DATE IN: August 13, 2001****Itemized Papers/Items:**

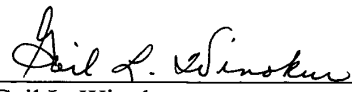
1. This certificate and a Return Receipt Postcard (2 pgs.)
2. Transmittal Form (1 pg.)
3. Fee Transmittal (1 pg. X 2)
4. Response to Notice of Missing Parts (1pg.) and copy of Notice to File Missing Parts (2 pgs.)
5. Executed Declaration of the Joint Inventors (4 pages)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

BOX PCT  
Commissioner for Patents  
Washington, D.C. 20231.

on this date, 8/13/01

Dated: 8/13/01

  
Gail L. Winokur

PTO/PC Rec'd

AUG 2001

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 09/673,958

Filed: 10/19/2000

1<sup>st</sup> Inventor: NANBA, N.For: A Human Derived Immortalized Liver Cell  
Line

Atty. Dkt. No. 2519 US0P

Art Unit: tba

Examiner: tba

Allowed:

Batch:

Paper No.:

FEDERAL ASSOCIATION	
DEFECTIVE RESPONSE NO.	
50	0799
115	110 00

RESPONSE to Notice of Defective Response

BOX PCT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Notice of Defective Response mailed July 11, 2001, Applicants respectfully submit the attached Executed Declaration of the Joint inventors.

Also enclosed is a copy of the Notice, and a Fee transmittal sheet (with copy).

The Commissioner is authorized to charge the appropriate surcharge under 37 CFR

1.492(e), or any additional fees, to USPTO Deposit account No. 500799.

09/21/2001 SNAJARRO 00000005 500799 09673958

01 FC:115 110.00 CH

Respectfully submitted,

Dated: August 10, 2001

(847)383-3372

(847)383-3391



Mark Chao, Ph.D., Reg. No. 37,293

Elaine M. Ramesh, Ph.D., Reg. No. 43032

Attorney for Applicants

Customer No. 23115

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
Suite 500, 475 Half Day Road  
Lincolnshire, IL 60069 USA



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents,  
United States Patent and Trademark Office  
Washington, DC 20503

U.S. APPLICATION NO.

09/673958

FIRST NAMED APPLICANT

NANBA

N

ATTY. DOCKET NO.

2519USOP

INTERNATIONAL APPLICATION NO.

PCT/JP99/02224

I.A. FILING DATE

27 APR 99

PRIORITY DATE

28 APR 98

DATE MAILED:

11 JUL 2001

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
SUITE 500  
LINCOLNSHIRE, IL 60069

## NOTIFICATION OF A DEFECTIVE RESPONSE

1. ☐ The request for an extension of time (37 CFR 1.136(a)) filed \_\_\_\_\_ is defective because the required fee is missing/insufficient. Extension of time fees are listed at 37 CFR 1.17(a)(1)-(a)(5).
2. ☐ Applicant's response filed \_\_\_\_\_ was received in the Office after the expiration of the period for response set in the Office notification mailed \_\_\_\_\_. This application will become abandoned unless applicant obtains an extension of time to reply to the last Office notification under 37 CFR 1.136(a).
3. ☒ Applicant's response filed 21 MAR 2001 is hereby acknowledged. The following requirements set forth in the NOTIFICATION of MISSING REQUIREMENTS (Form PCT/DO/EO/905) mailed 21 MAY 2001 have not been completed.

- ☐ Translation of the international application into English.  
☐ which is defective for the reasons indicated on the attached Notice of Defective Translation.
- ☐ Processing fee (37 CFR 1.492(f)).
- ☒ Oath or Declaration of inventor(s).  
☒ not in compliance with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
- ☒ Surcharge (37 CFR 1.492(e)).
- ☐ Sequence Listing.  
☐ not in compliance with 37 CFR 1.821-1.825 for the reasons indicated on the attached PCT/DO/EO/920.
- ☐ Additional claim fees.

Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements (Form DO/EO/905), whichever is the longer. No extension of this time limit may be granted under 37 C.F.R. § 1.136, but the period for response set in the Notification of Missing Requirements (Form DO/EO/905) may be extended under 37 C.F.R. § 1.136(a).

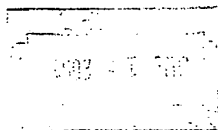
Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

Enclosed: ☐ PCT/DO/EO/917 ☐ Notice of Defective Translation  
☐ PCT/DO/EO/920

Anita D. Johnson

Telephone: 703-305-3661

FORM PCT/DO/EO/916 (March 2001)



U.S. APPLICATION NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/673958	NANBA	N 2519USOP
INTERNATIONAL APPLICATION NO.		
PCT/JP99/02224		
LA FILING DATE	PRIORITY DATE	
27 APR 99	28 APR 98	
DATE MAILED: 12 JUL 2001		

TAKEDA PHARMACEUTICALS AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
SUITE 500  
LINCOLNSHIRE, IL 60069

### NOTIFICATION OF A DEFECTIVE OATH OR DECLARATION

This application fails to contain an oath or declaration acceptable under 35 U.S.C. 371 (c)(4) for entry into the national stage in the United States of America. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action.

A new oath or declaration, identifying this application by the international application number and international filing date is required. The oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:

1. ☒ is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
2. ☐ does not identify the specification to which it is directed.
3. ☐ does not identify the inventor(s).
4. ☐ does not identify the citizenship of each inventor.
5. ☐ does not state the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

FAILURE TO SUBMIT AN OATH OR DECLARATION IN COMPLIANCE WITH 37 CFR 1.497(a) AND (b) WITHIN THE TIME PERIOD SET WILL RESULT IN FAILURE TO ENTER THE NATIONAL STAGE AND THE ABANDONMENT OF THE APPLICATION.

Additionally, the oath or declaration does not comply with 37 CFR 1.63 in that it:

1. ☐ does not identify the city and state or city and foreign country of residence of each inventor.
2. ☐ does not state that the person making the oath or declaration:
  - a. ☐ has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
  - b. ☐ acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.
3. ☐ does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.
4. ☐ does not state that the person making the oath or declaration acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and filing date of the continuation in part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)).

Anita D. Johnson  
Telephone: 703-305-3661

FORM PCT/DO/EQ/917 (September 1996)

5. # Each inventor's NAME must appear on each declaration.